WishBone Medical Plate and Screw System

Instructions for Use
WishBone Medical Plate and Screw System

Manufacturer:

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5.1.1	**Manufacturer**
5.1.3	Date of Manufacture
5.4.2	• **Single-use**
REF 5.1.6	• **Catalog number**
LOT 5.1.5	• **Lot number**
5.4.3	• **See instructions for use**
5.4.4	**Caution: See instructions for use**
STERILE R 5.2.3	• **Sterile – Irradiation**
STERILE EO 5.2.3	• **Sterile – ethylene oxide**
5.1.4	• **Use by date**
Rx only	**Caution: Federal law restricts this device to sale by or on the order of a physician.**
QTY	**Quantity**
5.2.6	**Do not resterilize**
	Not made with Natural Rubber Latex
5.2.8	**Do not use if package is damaged**

Symbols: ISO-15223

CONTENTS
The package contains one or several implants and surgical instrument(s) for the express purpose of fracture managment or deformity correction. Also available are individually sterilized and packaged ancillary screw implants, and screw kits.

DESCRIPTION
The WishBone Medical Plate and Screw System gives the surgeon a means of bone fixation and helps in the management of fractures and reconstructive surgery; bone plates are not intended to replace normal body structures. The WishBone Medical Plates and Screws are made of stainless steel or titanium alloy.

IMPLANT AND INSTRUMENT MATERIAL SPECIFICATIONS
Implants are made from medical grade stainless steel or titanium alloy; instruments are made from medical grade stainless steel and plastic.

MRI SAFETY INFORMATION
These devices have not been evaluated for safety and compatibility in the MRI environment. The system has not been tested for heating, migration, or image artifact in the MRI environment. The safety of these devices in the MRI environment is unknown. Scanning a patient who has this device may result in patient injury.

INTENDED USE
The WishBone Medical Plate and Screw System is used for pediatric and adult patients as indicated for pelvic, small and long bone fracture fixation and fixation of bones that have been surgically prepared (osteotomy) for correction of deformity or arthrodesis.

INDICATIONS
Indications for use include fractures of the clavicle, scapula, humerus, ulna, radius, middle hand, metacarpals, pelvis acetabulum, femur, fibula, tibia, metatarsals and middle foot bones, and treatment of the calcaneus.

ADVERSE EFFECTS
Possible reactions may include but are not limited to:
- Allergic reactions to metal
- Delayed or non-union of bone
- Delayed healing
- Delay of surgery
- Injury to user
- Adverse biologic reaction
- Revision
- Pain
- Infection
- Implant failure
- Difficulty in removal of hardware

CONTRAINDICATIONS
- Comminuted bone surface which would mitigate against plate and screw placement.
- Pathologic conditions of bone such as osteopenia which would severely impair the ability to securely fix the plate.
- Foreign body sensitivity to metals including nickel. Where material sensitivity is suspected, appropriate tests should be made prior to implantation.
- WishBone Medical Plate and Screw System plates are not intended to cross active growth plates.

HOW SUPPLIED/STORAGE
The devices are packed in protective packaging that is labeled to its contents. All implants and instruments are supplied sterile.
- Always store the devices in the original protective packaging.
- Store the devices in a dry and dust-free place (standard hospital environment).

STERILE
Procedure kits are sterilized by gamma irradiation, and ancillary screws are sterilized via ethylene oxide. Do not use if package is visibly open or damaged. Caution: Do not resterilize. This is a single-use device. Products intended for single-use must not be reused in a subsequent procedure. Reuse or reprocessing (e.g., cleaning and resterilization) may compromise the structural integrity of the device and/or lead to device failure which may result in patient injury, illness or death. Furthermore, reuse or reprocessing of single-use devices may create a risk of contamination due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user.

INSPECTION
Before use, inspect the implant/instrument box carefully. Do not use when sterile barrier is visibly damaged.

WARNINGS
Please note that using a single-use device which comes into contact with human blood or tissue constitutes reprocessing and that reprocessing can only be performed by an authorized third-party reprocessor who has received 510(k) clearance for such.

SAFETY PRECAUTIONS
- Prior to use, thoroughly read these instructions. Each surgeon must consider the particular needs of each patient and create a surgical plan that uses the appropriate implant(s) for that patient. Take care not to place screws into the physis of patients with open growth plates. Do not affix screws to the same plate both proximal and distal to a physis in patients with open growth plates.
- Keep the instructions for use accessible to all staff.
- The use of surgical instruments for tasks other than those for which they are intended may result in damaged or broken instruments or patient injury.
- The surgeon must be familiar with the instrumentation, method of application, and the recommended surgical technique for adequate fracture repair and protection of soft tissue structures during surgery. Use appropriate drill guide when drilling to protect soft tissues from the edges of drill flutes.
- Note: Due to the notch sensitivity of titanium, take care not to notch the plate when bending. The plate must never be unbent or reverted to its original shape once it has been contoured.
- Do not bend plates excessively. Do not use threaded drill guides to bend plates.
- Always confirm correct drill diameter for desired screw prior to drilling. Progress slowly with drill to prevent plunging through far cortex where vital anatomic structures might be. Fluoroscopy may be needed to confirm desired length.
- Always measure the depth of a pre-drilled hole by carefully inserting the depth gauge first through the plate, and then into the pre-drilled hole. The sleeve of the depth gauge must be fully inserted into the respective plate hole prior to measuring.
- Threaded drill guides must always fit securely within a locking hole. Using the wrong size or type of drill guide or angulating a threaded drill guide could cause the screw head to pull through the hole. Prior to screw insertion, confirm that the screw type (cortex or locking), length, and diameter is correct. Fluoroscopy may be needed to confirm desired length.
- Use manual force only with the screwdriver supplied to insert screws. Insert a screw only once. Do not reuse screws as fatigue or damage from a prior insertion may damage the screw.
- For one procedure only. Do not resterilize.
- Do not use if package is visibly open or damaged.

SAFETY PRECAUTIONS (CONT.)
- Do not use implants of dissimilar metals in contact with one another (i.e. titamiun screws with stainless steel plate) given the potential for corrosion.
- This is a single-use device. Never reuse an implant or instrument. Reuse can result in the transfer of materials including but not limited to bone, tissue, blood or infectious disease. Although the device may appear undamaged, previous stresses may have created nonvisible damage that could result in device failure. The manufacturer accepts no responsibility for a reused implant or instrument.
- This device is provided sterile and resterilization of the device has not been validated.
- WishBone Medical implants should only be used in conjunction with WishBone Medical instruments applicable for the respective sizes.
- After fracture reduction: When using locked plating techniques, reduction should, where possible, be within 1mm to limit fracture fragment motion during healing.
- After closure: For unstable repair constructs, i.e., highly comminuted fractures, post-operative loading should be restricted to a level determined by the physician until callus formation is radiographically documented.

SURGICAL TECHNIQUES
Surgical techniques describing the uses of this system are available. It is the responsibility of the surgeon to be familiar with the procedure before use of these products. In addition, it is the responsibility of the surgeon to be familiar with relevant publications and to consult with experienced associates regarding the procedure before use. Surgical techniques can be found on the WishBone Medical website (www.wishbonemedical.com).

Screw-only procedure instructions:
1. Select the associated drill bit based on the screw diameter and attach to drill.
2. Using the double-ended drill guide with the appropriate diameter based on the drill, carefully drill through both cortices of bone.
3. Using the depth gauge, measure for the appropriate screw length.
4. Select screw length and using the T15 screwdriver; manually insert the screw.
5. Confirm final screw placement (length, trajectory, and growth plate avoidance) using fluoroscopy.

Removal instructions: Using the single-use, sterile packed, WishBone Plate and Screw System screwdriver(s) carefully remove screw. Properly dispose of the screws and do not resterilize or reuse.

DEVICE INTENDED TO BE USED BY A TRAINED PHYSICIAN
This description alone does not provide sufficient background for direct use of WishBone Medical products. Instruction by a surgeon experienced in handling these products is highly recommended.

FOR FURTHER INFORMATION
Please contact WishBone Medical, Inc. or your authorized representative for further information about this product.

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